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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,801	11/12/2003	Francine M. Foss	00398-152001 / NEMC 263;	6989

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,801	FOSS ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Election/Restriction

1 Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 31-33, drawn to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:1, classified in class 530, subclass 350.

II. Claims 12-19, drawn to an isolated nucleic acid comprising a specific nucleotide sequence, a vector comprising said nucleic acid, a cell comprising said nucleic acid molecule, classified in class 435, subclass 69.1

III. Claim 20, drawn to an antibody that selectively binds to a polypeptide, classified in class 530, subclass 389.1.

IV. Claims 21, 24-28, drawn to a method of treating a patient by administering a polypeptide, classified in class 514, subclass 12.

V. Claims 22-23, drawn to a method of treating a patient by administering a composition comprising a nucleic acid, classified in class 514, subclass 44.

VI. Claims 29-30, drawn to a method of inhibiting the proliferation of a cell by contacting the cell with a polypeptide, classified in class 536, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group I and nucleic acid of Group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids,

and nucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a nucleic acid and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Although the nucleic acid of Group II can be used to produce the polypeptide of Group I, the polypeptide of Group I can also be recovered from a natural source using by biochemical means or by chemical synthesis. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups I and II are patentably distinct.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the nucleic acids are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. The databases used to search the sequences of polypeptides are not the same databases used to search nucleic acid sequences. As such, it would be burdensome to search the inventions of Groups I and II together.

The polypeptide of Group I and the antibody of Group III are patentably distinct for the following reasons:

While the inventions of both Group I and Group III are polypeptides, in this instance the polypeptide of Group I is a single chain molecule that functions as an cytokine, whereas the polypeptide of Group III encompasses antibodies including IgG

which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of Group I and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of Group I and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group I may be known even if a polypeptide of Group I is novel. In addition, the technical literature search for the polypeptide of Group I and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The nucleic acid of Group II and the antibody of Group III are patentably distinct for the following reasons. The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6

complementarity determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and nucleic acid, which are composed of nucleotide sequence, are structurally distinct molecules; any relationship between a nucleic acid and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a nucleic acid of Group II will not encode an antibody of Group III, and the antibody of Group III cannot be encoded by a nucleic acid of Group II. Therefore the antibody and nucleic acid are patentably distinct.

The antibody and nucleic acid inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group II and Group III would impose a serious search burden since a search of the nucleic acid of Group II would not be used to determine the patentability of an antibody of Group III, and vice-versa.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process. In the instant case, the polypeptide of group I as claimed can be used diagnostically or can be used to raise antibodies.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process. In the instant case, the polypeptide of group I as claimed can be used therapeutically or can be used to raise antibodies.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process. In the instant case, the nucleic acid of group II as claimed can be used in a method of producing the encoded polypeptide.

Inventions II and III are unrelated to inventions IV and VI, because neither the nucleic acid of Group II, nor the antibody of Group III, is used or produced in the processes of Groups IV or VI.

Inventions I and V are unrelated, because neither the polypeptide of Group I, is neither used nor produced in the process of Group V.

Inventions IIV-VI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has

prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
20 September 2005

JOSEPH MURPHY
PATENT EXAMINER